18. The method of claim 11 wherein and the antibiotic dissolves at a rate within the range of 30 to 35 percent in 15 minutes, 65 to 75 percent in 30 minutes, and 90 to 100 percent in 45 minutes.

REMARKS

Claims 1-18 are pending in the application. Claims 10-18 are added herein. Support for new claims 10-18 can be found, for example at pages 3-7 of the specification. In view of the following remarks, applicant believes all of the claims pending in the application are in condition for allowance.

On page 2 of the office action, the Examiner rejected claims 1-9 under 35 U.S.C. § 103(a) as being unpatentable over Fuisz (USP 5,518,730) in view if Williams et al. The examiner noted that "Fuisz teaches the administration of a controlled release oral dosage form comprising tetracycline" wherein the occurrence of certain side effects, not including vestibular side effects, are minimized or eliminated. The examiner further noted that Williams teaches the occurrence of vestibular side effects following tetracycline administration.

In response applicant notes that Fuisz is directed very generally to "biodegradable controlled release delivery systems . . . for bio-effecting agents." Fuisz, Abstract. While Fuisz does include the bald assertion that an advantage of such a system is the "minimization or elimination of local and/or systemic side effects," Fuisz discloses and claims that hundreds of "bio-effecting agents" may be useful in connection with his invention. Yet Fuisz fails to identify any specific side effects that can be eliminated or minimized in this way. Presumably Fuisz does not mean that all side effects of whatever nature caused by all "bio-effecting agents" can be avoided in this way, but one of ordinary skill in the art has no way of determining from Fuisz what side effects might be affected. Thus, the alleged teaching of Fuisz is the proverbial needle-

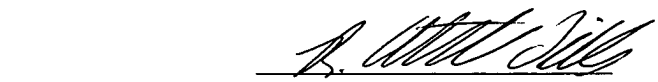
in-a-haystack and the examiner is proposing an "obvious to experiment" standard that has been expressly rejected by the Federal Circuit. See, e.g., In re Dow Chemical Co., 837 F.2d 469, 473, 5 USPQ2d 1529 1532 (Fed. Cir. 1989)("obvious to experiment" standard for obviousness rejected); In re Clinton, 527 F.2d 1226, 1228, 188 USPQ 365, 367 (CCPA 1976) ("Obviousness does not require absolute predictability but a reasonable expectation of success is necessary."). Fuisz alone creates no reasonable expectation that any particular side effect caused by any particular pharmaceutical can be minimized eliminated through the use of a controlled release delivery vehicle. Fuisz certainly does not create a reasonable specific expectation that vestibular side effects caused by orally administered tetracyclines can be minimized or eliminated with a controlled release vehicle. Williams fails to suggest anything other than that vestibular side effects may be caused by minocycline. In short, nothing in either Fuisz and/or Williams creates a reasonable expectation that administering oral tetracycline antibiotic in a slowly dissolving dosage form will reduce the incidence or severity of vestibular side effects resulting therefrom as set forth in claim 1.

Thus, neither Fuisz nor Williams, whether considered alone, together, or with any other reference of record teach or suggest a method for reducing the incidence or severity of vestibular side effects resulting from the treatment of acne by the use of oral tetracycline antibiotics as set forth in claim 1. Applicant submits, therefore, that the rejection of claim 1 under 35 U.S.C. § 103 is improper and should be withdrawn. Further, since claims 2-9 depend variously from claim 1, applicant submits that the rejections of claims 2-9 under 35 U.S.C. § 103 are likewise improper and should be withdrawn. Moreover, claims 3-9 contain various limitations concerning the antibiotic dissolution rates. None of these limitations are taught or suggested by the references of record. Thus, for this reason as well, the rejections of claims 3-9 under 35 U.S.C. § 103(a) are improper and should be withdrawn.

As set forth in new claim 10, applicant's invention is directed to: a method for reducing the incidence or severity of vestibular side effects resulting from the treatment of acne by the use of oral tetracycline antibiotics, comprising administering the oral tetracycline antibiotic in a slowly dissolving dosage form, wherein the dissolution of the antibiotic is substantially complete in less than 24 hours. Fuisz teaches a controlled release delivery system that delivers a "bio-effecting agent" over a period of 6 to 14 days or more not over a period of less than 24 hours. Thus, even if Fuisz, alone or in combination with Williams, did teach a method for reducing vestibular side effects of orally administered tetracycline, which it does not, Fuisz, alone or in combination with Williams, clearly does not teach such a method in which the dissolution of the antibiotic is substantially complete in less than 24 hours.

In view of the foregoing amendments and remarks, Applicant requests reconsideration and further examination of the present application. Applicant submits that all pending claims are in condition for allowance. Applicant respectfully requests an early and favorable action on the merits.

Respectfully submitted,



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